

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 180-206 were previously pending in this application. No claims have been amended, added, withdrawn or canceled. As a result, claims 180-206 remain pending for examination with claims 180, 189, 192, 198, 201 and 205 being independent claims. No new matter has been added.

#### **Interview Summary**

Applicant thanks Examiners Helms and Aeder for the courtesy of a telephone interview with Applicant's Assignee's representative. During the interview, Applicant's Assignee's representative discussed with the Examiner the rejection under 35 U.S.C. §103 as well as the statements made by Examiner Aeder in his Advisory Action of May 28, 2009. Applicant's Assignee's representative provided arguments to rebut the aforementioned obviousness rejection, some of which were arguments previously made of record and/or were discussed in a prior interview with Examiner Aeder. Examiner Helms, in considering the rejection under 35 U.S.C. §103, suggested that the rejection may be withdrawn. Applicant's Assignee's representative offered to submit a Supplemental Response to further address the rejection and to provide an interview summary to be of assistance to the Examiners.

#### **Rejection Under 35 U.S.C. §103**

Claims 201-206 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Dumas et al. (EP 1 033 401 A2) ('Dumas') in view of Altman et al. (Science, 1996, 274:94-96) ('Altman'). In the Examiner's Advisory Action of May 28, 2009, the Examiner argued that Dumas teaches that all of the polypeptides are to be evaluated for their effects on cytotoxic lymphocytes and that, accordingly, the compositions of the rejected claims, which would predictably function in methods of evaluating said effects, are rendered obvious.

Applicant respectfully disagrees. As argued previously, it is Applicant's position that the pending claims are not obvious in view of the cited references and that the Examiner has failed to establish a proper *prima facie* case of obviousness. Based on the teachings of the cited references there is no reason for a skilled artisan to select the polypeptide of SEQ ID NO:4557 out of the more than 4000 polypeptides provided. In addition, there is no reason for a skilled

artisan to choose to assess the effect of this, or any, polypeptide on cytotoxic lymphocytes out of all of the possible effects mentioned in Dumas. There is nothing provided that would lead to the selection of a particular polypeptide or to a particular effect of Dumas.

The analysis supporting a rejection under 35 U.S.C. §103 “cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). (original citations omitted). In Takeda Chemical Industries, LTD. v. Alphapharm PTY., LTD., 492 F.3d 1350 (Fed. Cir. 2007), which was decided post-KSR, Alphapharm asserted that compounds claimed in a Takeda patent were invalid as obvious in view of a lead compound which was disclosed in the prior art, and which parties agreed was the closest prior art compound. Alphapharm argued that the prior art would have led one of ordinary skill in the art to select the lead compound from among a genus of fifty-four compounds, which had been specifically identified in a patent document disclosing millions of other related compounds, and modify that lead compound with two obvious chemical changes to arrive at the compound claimed in the Takeda patent, thereby rendering it invalid. *Id.* at 1357. The Federal Circuit was not persuaded by Alphapharm’s assertions on multiple grounds and upheld the district court’s ruling that the claimed compounds were unobvious in view of the prior art, reasoning, in part, that when the prior art discloses a vast number of compounds as possible lead compounds (starting points) there must be something in the prior art to “narrow the possibilities” to the particular lead compound that is to form the basis of an obviousness rejection. *Id.* at 1358.

Similar to the failure of Alphapharm’s obviousness assertion, this rejection fails as there is nothing in the prior art cited by the Examiner to “narrow the possibilities” to the particular lead compound (in this case the polypeptide of SEQ ID NO: 4557) or to the particular effect on cytotoxic lymphocytes. The Examiner states that Dumas teaches that all polypeptides are to be evaluated for their effect on cytotoxic lymphocytes. However, this is not the case. Dumas only refers to “proteins or polypeptides” generically, and this is not a teaching that any specific polypeptide, subset of polypeptides, or even all of the polypeptides should be tested. Again, over 4000 polypeptides are provided in Dumas.

In addition, there is nothing in the prior art that would direct one of ordinary skill to test any particular polypeptide for any of the multitude of possible effects mentioned in Dumas. While Dumas states that the effect on cytotoxic lymphocytes by the polypeptides, generically, may be assessed, Dumas also indicates that the polypeptides may also be tested for binding to cell surfaces (Example 21); cytokine, cell proliferation or cell differentiation activity (Example 22); immune system regulation activity (Example 23); hematopoietic regulation activity (Example 24); tissue growth regulation activity (Example 25); reproductive hormone regulation activity (Example 26); activity as a chemotactic/chemokinetic agent (Example 27); blood clotting regulation activity (Example 28); activity in receptor/ligand interactions (Example 29); activity as an anti-inflammatory agent (Example 30); activity as a tumor inhibitor (Example 31); etc. Nothing in the cited references would direct one of ordinary skill in the art to assess any particular effect.

As a result, the claims are not obvious in view of the cited references. No sufficient reason is provided to demonstrate that one of ordinary skill in the art would select a polypeptide of Applicant's claims and combine it with an adjuvant, cytokine, or a costimulatory molecule in a composition.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. L0461.70156US00.

Respectfully submitted,



Janice A. Vatland, Ph.D.  
Registration No.: 52,318  
WOLF, GREENFIELD & SACKS, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
617.646.8000

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